AF JFW

MISC. FEE TRANSMITTAL

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT

Complete if Known	
Application Number	10/010,678
Filing Date	December 7, 2001
First Named Inventor	G.J. Gormley et al.
Examiner Name	V.Y. Kim
Group Art Unit	1618
Attorney Docket Number	19109DE

METHOD OF PAYMENT

☒ Deposit Account

Deposit Account Number 13-2755 Deposit Account Name Merck & Co., Inc.

The Director is authorized to:

☐ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17

FEE CALCULATION

FEES
Large Entity

Fee Code	Fee ($)	Fee Description	Fee Paid
1051	130	Surcharge - late filing fee or oath	
1051	130	Non-English Specification	
1812	2,520	For filing a request for *ex parte* reexamination	
1402	500	Filing a brief in support of an appeal	
1452	500	Petition to revive - unavoidable	
1453	1,500	Petition to revive - unintentional	
1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	Submission of Information Disclosure Statement	
1809	790	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	790	For each additional invention to be examined (37 CFR 1.129(b))	
1840	130	Statutory Terminal Disclaimer under 37 CFR 1.321	
		Other fee (specify) Response to Non-Compliant Appeal Brief due 12-30-2005	
		Other fee (specify)	

TOTAL $0

SUBMITTED BY				Complete (if applicable)	
Typed or Printed Name	CATHERINE D. FITCH			Reg. Number	36,502
Signature	Catherine D Fitch	Date	12/14/2005	Deposit Account User ID	

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s): G.J. Gormley et al.

Application Number: 10/010,678 Case No.: 19109DE

Filing Date: December 7, 2001

Title of the Invention: TRANSDERMAL TREATMENT WITH 5-ALPHA-REDUCTASE INHIBITORS *(as amended)*

Examiner: V. Y. Kim

Art Unit: 1618

APPEAL BRIEF

37 C.F.R. 1.8 Certificate of Mailing

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents P.O. Box 1450 Alexandria VA 22313-1450, on the date appearing below.

MERCK & CO., INC.

By _____ Date December 14, 2005

Anita G. Brown

TABLE OF CONTENTS

REAL PARTY IN INTEREST

The real party in interest is Merck & Co., Inc., of Rahway, New Jersey, by assignment recorded at the U.S. Patent and Trademark Office on April 26, 1996 (Reel 7916/Frame 0548). The inventors of the present application assigned their interests to Merck & Co., Inc., in an assignment executed April 25, 1994.

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to the Appellants, or known to Appellants' legal representative, that will directly affect the Board's decision in the pending appeal, other than the earlier appeal in the present application, Appeal No. 2004-0543, decision mailed December 29, 2004.

STATUS OF CLAIMS

Claims pending: 28-37.
Claims cancelled: none.
Claims allowed: none.
Claims rejected: 28-37.
Claims on appeal: 28-37.

STATUS OF AMENDMENTS

An amendment under 37 CFR 1.116 was filed June 24, 2005, in response to and subsequent to the May 6, 2005, final rejection. This amendment was not entered as the Examiner contended it raised new issues requiring further consideration and/or search, because the claims were narrowed and could require a new search. This is referred to as the "fifth amendment" in the description below.

One preliminary amendment and four amendments were filed for this application. A preliminary amendment was filed on December 7, 2001, accompanying a new divisional application under 37 CFR 1.53(b) based on parent Application Serial No. 09/699,906. A second amendment under 37 CFR 1.111 was filed October 16, 2002. The two amendments were entered by the Examiner. Subsequently, A third amendment under 37 CFR 1.116 was filed April 25, 2003, (following a Final Office Action), but was never entered by the Examiner because the

Examiner stated it raised new issues that would require further consideration and/or search. A Notice of Appeal was timely filed April 25, 2003, and a Decision on Appeal (Appeal No. 2004-0543) was mailed December 29, 2004. The Decision on Appeal raised a new ground of rejection under 37 CFR 41.50(b)(1), for which an amendment (the fourth) was timely filed January 27, 2005. The list of claims presented in Appendix I reflects entry of these amendments. A fifth amendment under 37 CFR 1.116 was filed June 24, 2005, in response to the May 6, 2005, final rejection. This amendment was not entered as the Examiner contended it raised new issues requiring further consideration and/or search, because the claims were narrowed and could require a new search.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention as defined in Claims 28-32 under appeal relates to a method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor. The invention defined in Claims 33-35 under appeal relates to a method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one. The invention defined in Claims 36-37 under appeal relates to a transdermal skin patch comprising a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor. A copy of the claims appears in the CLAIMS APPENDIX.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

There is one issue being presented for review by the Board of Appeals. The issue on appeal is the rejection of Claims 28-37 under 35 U.S.C. § 103(a) as being unpatentable over Goldman, US 5,407,944. Appellants believe the rejection to be erroneous, as will be explained in the Argument Section that follows.

ARGUMENT

I. Claims 28 to 37 are not obvious under 35 U.S.C. § 103(a) as being unpatentable over US 5,407,944.

As set forth in detail below, Appellants submit that the methods for treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such

treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one as defined by Claims 28, 29 and 31-34, the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, in a transdermal skin patch, as defined by Claims 30 and 35, and the transdermal skin patch consisting essentially of a 5-alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient as defined by Claims 36 and 37, are nonobvious over the cited references. Applicants submit that the Board of Appeals should reverse the Examiner's rejections of Claims 28-37. Favorable action by the Board is respectfully requested.

A. The § 103 (a) Obviousness Rejection of Claims 28,29 and 31-34 over US 5,407,944 is Improper

Claims 28, 29 and 31-34 specify that the method of treating androgenic alopecia consists essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor. US 5,407,944 to Goldman teaches a method for promoting hair growth comprising administering a therapeutically effective amount of at least two active agents. These active agents are selected from vasodilators, estradiols, 5alpha-reductase inhibitors and salts, esters and prodrugs thereof. US 5,407,944 does not teach or even suggest the method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha reductase inhibitor. Indeed, in the only exemplification in US 5,407,944, the 5alpha-reductase inhibitor is used in prophetic examples (1) with a vasodilator and estradiol, in a 3 ingredient treatment (US 5,407,944 col. 8, line 68-col. 9, line 2) and (2) with a vasodilator and a 5alpha-reductase inhibitor in a 2 ingredient combination (Ibid., col. 9, lines 3-4).

Contrary to the Examiner's contention, the expression "consisting essentially of" does not permit additional active ingredients, such as vasodilators and estradiol. Consisting essentially of excludes other elements from having any essential significance to the combination. The additional ingredients in US 5,407,944 useful for growing hair are elements that would have essential significance in the combination. "Consisting essentially of" permits a degree of "reading on" additional unspecified substances which do not affect the basic and novel characteristics of the claimed invention. See, Practicing Law Institute, Landis On Mechanics of

Patent Claim Drafting, 1997, § 8. However, additional active ingredients do affect the basic characteristics of the claimed invention and are not encompassed by the presently drafted claims.

B. The § 103 (a) Obviousness Rejection of Claims 30 and 35 over US 5,407,944 is Improper

Claims 30 and 35 depend from Claims 28 and 31, respectively, further distinguish the present invention and add the limitation that the 5alpha-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, is administered via transdermal patch. US 5,407,944 does not teach or suggest administration of a 5alpha-reductase inhibitor via transdermal patch. US 5,407,944 does describe several formulations in the patent; namely:

(1) Minoxidil as a topical solution (col. 3, lines 39-52);
(2) Minoxidil in tablet form (col. 3, lines 53-62);
(3) Nitroglycerin as a transdermal system (col. 4, lines 1-6);
(4) Diazoxide as a capsule or suspension (col. 4, lines 7-18);
(5) Nifedipine as a capsule (col. 4, lines 19-38);
(6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
(7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5,line 28);
(8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);
(9) Finasteride as a tablet (col. 5, lines 43-62).

Of the nine formulations listed above from the US 5,407,944 patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the US 5,407,944 patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The US 5,407,944 patent at col. 6, lines 10 to 50, does not teach a transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g., 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), as asserted by the Examiner. In fact, read in context with the particular formulations US 5,407,944 teaches in the patent, US 5,407,944 teaches away from the administration of a 5alpha-reductase inhibitor via transdermal skin patch.

C. The § 103 (a) Obviousness Rejection of Claims 36 and 37 over US 5,407,944 is Improper

Claims 36 and 37 are directed to a transdermal skin patch consisting essentially of a 5alpha reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient. US 5,407,944 does not teach or suggest a transdermal skin patch consisting essentially of a 5alpha-reductase 2 inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient.

Goldman does not teach or suggest formulation of a 5alpha-reductase inhibitor in a transdermal patch. Goldman does describe several formulations in the patent; namely:

(1) Minoxidil as a topical solution (col. 3, lines 39-52);
(2) Minoxidil in tablet form (col. 3, lines 53-62);
(3) Nitroglycerin as a transdermal system (col. 4, lines 1-6);
(4) Diazoxide as a capsule or suspension (col. 4, lines 7-18);
(5) Nifedipine as a capsule (col. 4, lines 19-38);
(6) Nifedipine as a controlled release tablet for oral administration (col. 4, lines 42-56);
(7) 17beta-estradiol as tablet or cream (col. 4, line 57 to col. 5,line 28);
(8) 17beta-estradiol as a transdermal patch (col. 5, lines 29-42);
(9) Finasteride as a tablet (col. 5, lines 43-62).

Of the nine formulations listed above from the US 5,407,944 patent, only finasteride is a 5alpha-reductase inhibitor. Minoxidil, nitroglycerine, diazoxide, and nifedipine are vasodilators under the definition of the US 5,407,944 patent, and 17-beta estradiol is an estradiol. Although other compounds are taught to be present in topical solutions, transdermal systems, creams, or transdermal patches, the 5alpha-reductase inhibitor is taught only as a tablet. The US 5,407,944 patent at col. 6, lines 10 to 50, does not teach a transdermal skin patch comprising a composition containing 5α-reductase 2 inhibitor (e.g., 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), as the Examiner stated. In fact, read in context with the particular formulations US 5,407,944 teaches in the patent (cited above), US 5,407,944 teaches away from the transdermal skin patch consisting essentially of a 5alpha-reductase inhibitor, including 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one, as the active ingredient.

CONCLUSION

Appellants request that the Board of Patent Appeals and Interferences reverse the outstanding rejections of claims 28 to 37.

Please charge deposit account 13-2755 for fees due in connection with this appeal brief. If any time extensions are needed for the timely filing of the present appeal brief, appellants

petition for such extensions and authorize the charging of deposit account 13-2755 for the appropriate fees.

Respectfully submitted,

By _____

Catherine D. Fitch, Reg. No. 36,502
Attorney for Appellants

Merck & Co., Inc.
RY60-30
P.O. Box 2000
Rahway, NJ 07065-0907
(732) 594-4283

Date: December 14, 2005

CLAIMS APPENDIX

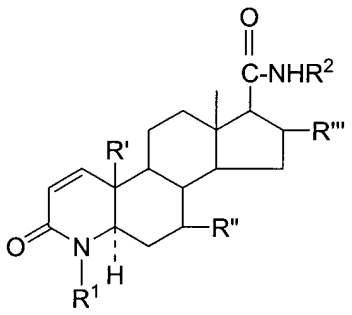
The claims on appeal are as follows:

Claim 28. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

Claim 29. The method according to Claim 28, wherein androgenic alopecia is male pattern baldness.

Claim 30. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

Claim 31. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula I:



I

or a pharmaceutically acceptable salt thereof wherein:

R^1 is hydrogen, methyl or ethyl;

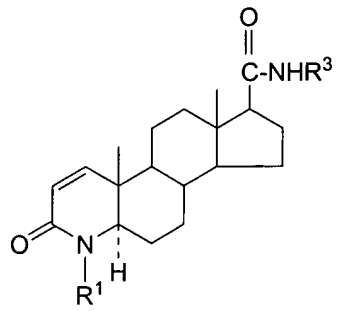
R^2 is a hydrocarbon radical selected from straight and branched chain alkyl of from 1-12 carbons or monocyclic aryl optionally containing 1 or more lower alkyl substituents of from 1-2 carbon atoms and/or 1 or more halogen substituents selected from Cl, F and Br;

R' is hydrogen or methyl;

R" is hydrogen or β-methyl; and

R''' is hydrogen, α-methyl or β-methyl.

Claim 32. The method according to Claim 28, wherein the 5alpha-reductase 2 inhibitor has the structural formula II:



II

or a pharmaceutically acceptable salt thereof, wherein:

R^1 is hydrogen or methyl; and

R^3 is branched chain alkyl of from 4 to 8 carbons.

Claim 33. A method of treating androgenic alopecia consisting essentially of transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

Claim 34. The method of Claim 33 wherein androgen alopecia is male pattern baldness.

Claim 35. The method according to Claim 33, wherein the 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one inhibitor is transdermally administered by a transdermal skin patch.

Claim 36. A transdermal skin patch consisting essentially of a therapeutically effective amount of a 5 alpha-reductase 2 inhibitor as the active ingredient.

Claim 37. The transdermal skin patch according to Claim 36 wherein the 5alpha-reductase 2 inhibitor is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

EVIDENCE APPENDIX

No evidence is provided by the appellant.

RÈLATED PROCEEDINGS

1. Board of Patent Appeals and Interferences Decision on Appeal No. 2004-0543, Application No. 10/010,678

CDF

19109DE

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 14

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GLENN J. GORMLEY, KEITH D. KAUFMAN, ELIZABETH STONER and JOANNE WALDSTREICHER

Appeal No. 2004-0543
Application No. 10/010,678

ON BRIEF

Before SCHEINER, MILLS and GRIMES, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the final rejection of claims 28-37, the only claims remaining. Claims 28, 30, 33 and 36 are representative:

28. A method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

30. The method according to claim 28, wherein the 5alpha-reductase 2 inhibitor is transdermally administered by a transdermal skin patch.

33. A method of treating androgenic alopecia comprising transdermally administering to a person in need of such treatment a therapeutically effective amount of 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one.

36. A transdermal skin patch comprising a therapeutically effective amount of a 5alpha-reductase 2 inhibitor.

The references relied on by the examiner are:

Goldman	5,407,944	Apr. 18, 1995
Rasmusson et al. (Rasmusson)	EP 0 285 382	Oct. 5, 1988

Claims 28, 29 and 31-34 stand rejected under 35 U.S.C. § 102(b) as anticipated by Rasmusson, while claims 30 and 35-37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Rasmusson and Goldman.

For the reasons which follow, we reverse the rejection of claims 28, 29 and 31-34 under 35 U.S.C. § 102(b); vacate the rejection of claims 30 and 35-37 under 35 U.S.C. § 103; and enter a new ground of rejection against claims 28-37 under the provisions of 37 CFR § 41.50(b).[1]

DISCUSSION

Anticipation by Rasmusson

According to the examiner, Rasmusson describes treating androgenic alopecia "using topical 5 alpha reductase inhibitors (e.g. 17-beta-N-monosubstituted-carbamoyl-4-aza-5alpha reductase inhibitors [like 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one]) . . . in the form of cream, lotion or ointment" (Answer, page 4) and thus meets "all the critical elements required by [claims 28, 29 and 31-34]" (id., page 5).

There is no dispute that Rasmusson describes the 5-alpha reductase inhibitors required by the present claims, rather, the issue is whether Rasmusson's "topical" administration of the inhibitor meets the present requirement for "transdermal" administration.

---

[1] The term "vacate," as applied to an action taken by an appellate tribunal, means to set aside or void. Black's Law Dictionary 1075 (abridged 6th ed. 1991). When the board vacates a rejection in favor of a new ground of rejection, the original rejection no longer exists. We emphasize that the board does not take an ultimate position on the correctness of an examiner's rejection when that rejection is vacated. See also Ex parte Zambrano, 58 USPQ2d 1312 (Bd.Pat.App. & Int. 2001).

Claims 28, 29 and 31-34 specifically require transdermal administration of the inhibitor. We agree with the examiner that "transdermal administration is broader than skin-patch administration" (Answer, page 8), but disagree with the examiner's assertion that "appellants prefer the claim language to be understood as 'use of [a] transdermal skin patch'" (id.).[2] Rather, appellants' position is essentially that "transdermal ('through-the-skin') administration constitutes a separate and distinct claim limitation from [ ] topical ('cutaneous') administration of 5alpha-reductase 2 inhibitors" (Brief, page 6), and "the two routes of administration are in fact not interchangeable" (id., page 7), because transdermal administration is systemic and continuous, while topical administration is local and intermittent (id., pages 7 and 8).

Appellants rely on two forms of evidence in support of their position: their original disclosure, and an excerpt from The Merck Manual.[3] With respect to their original disclosure, appellants argue that "the fact that [ ] transdermal administration and topical administration [are taught] in two different paragraphs [on page 6] suggests that the two routes of administration are not interchangeable" (Brief, page 7). Nevertheless, we find that there is some overlap between the two terms as they are used in the specification. That is, the specification teaches that "transdermal" administration is systemic and "continuous rather than intermittent" (Specification, page 7), but does not restrict

---

[2] The examiner's interpretation of appellants' argument appears to stem from appellants' statement on page 7 of the Brief that their "original patent disclosure [(at page 6, lines 22-24 and 32-34)] associates topical administration with 'solution[s], cream[s], ointment[s], gel[s], lotion[s], shampoo[s] or aerosol formulation[s]' . . . [while] transdermal administration is linked to the use of transdermal skin patches only."

[3] The Merck Manual, Second Home Edition, Chapter 11, Drug Administration and Kinetics, Thomas N. Tozer, Ph.D., Drug Administration, Appendix I; submitted with appellants' Brief as Appendix II, and available at http:// www.merck.com/pubs/mmanual_home2/sec02/ch011/ch011b.htm .

"topical" administration to local or intermittent administration. As used in the specification, "topical" administration can also include systemic administration: for example, the specification teaches that "5α-reductase 2 inhibitor compounds . . . can be administered in a wide variety of therapeutic dosage forms in conventional vehicles for systemic administration. For example, the compounds can be administered in such oral dosage forms as tablets, capsules [ ], pills, powders, granules, elixirs, tinctures, solutions, suspensions, syrups and emulsions. Likewise, they may also be administered in intravenous [form], intraperitoneal [form], subcutaneous [form], topical [form] with or without occlusion, or intramuscular form . . ." (Page 6, emphasis added).

Similarly, The Merck Manual teaches that drugs "may be applied to the skin (cutaneously) for a local (topical) or bodywide (systemic) effect; or delivered through the skin by a patch (transdermally) for a systemic effect" (Appendix II, page 1). Under the heading "Cutaneous Route," the manual indicates that "[d]rugs applied to the skin are usually used for their local effects and thus are most commonly used to treat superficial skin disorders . . . depending on the consistency of [ ] inactive substances, the formulation may be an ointment, a cream, a lotion, a solution, a powder or a gel" (id., page 3, emphasis added). Under the heading "Transdermal Route," the manual teaches that "[s]ome drugs are delivered bodywide through a patch on the skin. These drugs, sometimes mixed with a chemical (such as alcohol) that enhances penetration of the skin, pass through the skin to the bloodstream without injection. Through a patch, the drug can be delivered slowly and continuously for many hours or days . . . As a result, levels of a drug in the blood can be kept relatively constant" (id., pages 3-4).

Having reviewed the evidence of record, we find that the terms transdermal administration and topical administration are not always mutually exclusive. That is, while transdermal administration of a substance results in systemic administration ("through-the-skin" administration), topical administration can result in strictly local, or systemic administration – depending upon the carrier used. In other words, topical administration can, in some circumstances, include transdermal administration. Thus, the issue comes down to what Rasmusson means by "topical" administration.

Rasmusson describes "a method of treating the hyperandrogenic conditions of androgenic alopecia, including male pattern alopecia, acne vulgaris, seborrhea, and female hirsutism by topical administration, and a method of treating all of the above conditions as well as benign prostatic hypertrophy, by systemic administration" of 5 alpha reductase inhibitors (page 6, emphasis added). According to Rasmusson, "topical pharmaceutical compositions may be in the form of a solution, cream, ointment, gel, lotion, shampoo or aerosol formulation adapted for application to the skin" (id.), while "the active ingredient for use in the treatment of benign prostatic hypertrophy can be administered in a wide variety of therapeutic dosage forms in conventional vehicles for systemic administration, as, for example, by oral administration in the form of tablets, capsules, solutions or suspensions, of [sic] by intravenous injection" (id.).

We find (1) that Rasmusson's use of the term "topical" administration does not include systemic administration, and therefore, does not include "transdermal" administration; and (2) that none of the "vehicles for systemic administration" described in the reference are suitable for transdermal administration. Therefore, we conclude that Rasmusson does not anticipate the claimed invention, and the rejection of claims 28, 29 and 31-34 under 35 U.S.C. § 102(b) is reversed.

Unpatentability over Rasmusson and Goldman

Claims 30 and 35-37 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Rasmusson and Goldman. The underlying premise of the rejection is that Rasmusson describes transdermal administration of a 5α-reductase 2 inhibitor, and lacks only a description of a transdermal skin patch; the examiner relies on Goldman to make up this deficiency.

As discussed above, we do not agree that Rasmusson describes transdermal administration of a 5α-reductase 2 inhibitor. On the other hand, we agree with the examiner that Goldman is relevant to the claimed invention, but for reasons somewhat different than those of the examiner. Therefore, we vacate the examiner's rejection of claims 30 and 35-37 and enter the following new ground of rejection under the provisions of 37 CFR § 41.50(b).

NEW GROUND OF REJECTION UNDER 37 CFR § 41.50(b)

Claims 28-37 are rejected under 35 U.S.C. § 103(a) as unpatentable over Goldman. Claim 28 is directed to a method of treating androgenic alopecia comprising transdermally administering a 5-α-reductase inhibitor; claim 30 specifies administration by transdermal skin patch; claim 33 specifies that the 5-α-reductase inhibitor is 17β-(N-tert-butylcarbamoyl)-4-aza-5α-androst-1-ene-3-one), otherwise known as "finasteride;" claim 36 is directed to a skin patch comprising a 5-α-reductase inhibitor.

Goldman teaches that androgenic alopecia/male pattern baldness can be treated topically or systemically with a combination of three agents: a vasodilator; an estradiol; and 5-α-reductase inhibitor (column 2, lines 42-46; column 6, lines 5-9). "A highly preferred inhibitor of . . . 5-α-reductase for use in [Goldman's] compositions and

methods" (column 5, lines 43-44), indeed the only 5-α-reductase inhibitor specifically mentioned, is finasteride (column 5, lines 43-62). While "each agent of the combination need not be administered in the same manner" (column 2, lines 65-67), "in a highly preferred embodiment the selected agents are administered from a single vehicle in unit dosage form, including tablet, capsule, and transdermal patches or preparation" (column 3, lines 7-10).

While Goldman does not specifically describe incorporating a 5-α-reductase inhibitor into a transdermal skin patch and using the patch to treat androgenic alopecia, he explicitly suggests doing just that. Moreover, Goldman identifies finasteride as a "highly preferred" 5-α-reductase inhibitor for this purpose. It would have been obvious for one skilled in the art to have treated androgenic alopecia by transdermal administration of a pharmaceutical preparation, e.g., a transdermal skin patch, comprising a 5-α-reductase inhibitor, e.g., finasteride, in view of Goldman's explicit suggestions.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 CFR § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 CFR § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 CFR § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen Prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .

(2) *Request Rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

REVERSED; VACATED; 37 CFR § 41.50(b)

Toni R. Scheiner)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
)
Demetra J. Mills) APPEALS AND
Administrative Patent Judge)
) INTERFERENCES
)
)
Eric Grimes)
Administrative Patent Judge)

Catherine D. Fitch
Merck and Co., Inc.
P.O. Box 2000
Rahway, NJ 07065-0907